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2026 US Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



Japanese TMF community update : Recent highlights including TMF RM survey review

Yuto Kanda, Japan TMF community Lead, Chugai Pharmaceutical.Co.,Ltd,
Mai Nishihara, TMF TMF Operations Representative Chugai Clinical Research Center Co.,Ltd.

Agenda

1. JP TMF Community Overview
2. Reference Model Sub-Team Survey:
   Practitioner Insights for Future TMF Standards

Speakers



Yuto Kanda

Japan TMF community Lead

Chugai Pharmaceutical.co.ltd,



Mai Nishihara

TMF Operational Responsible

Chugai Clinical Research Center Co., Ltd.

JP TMF Community Overview

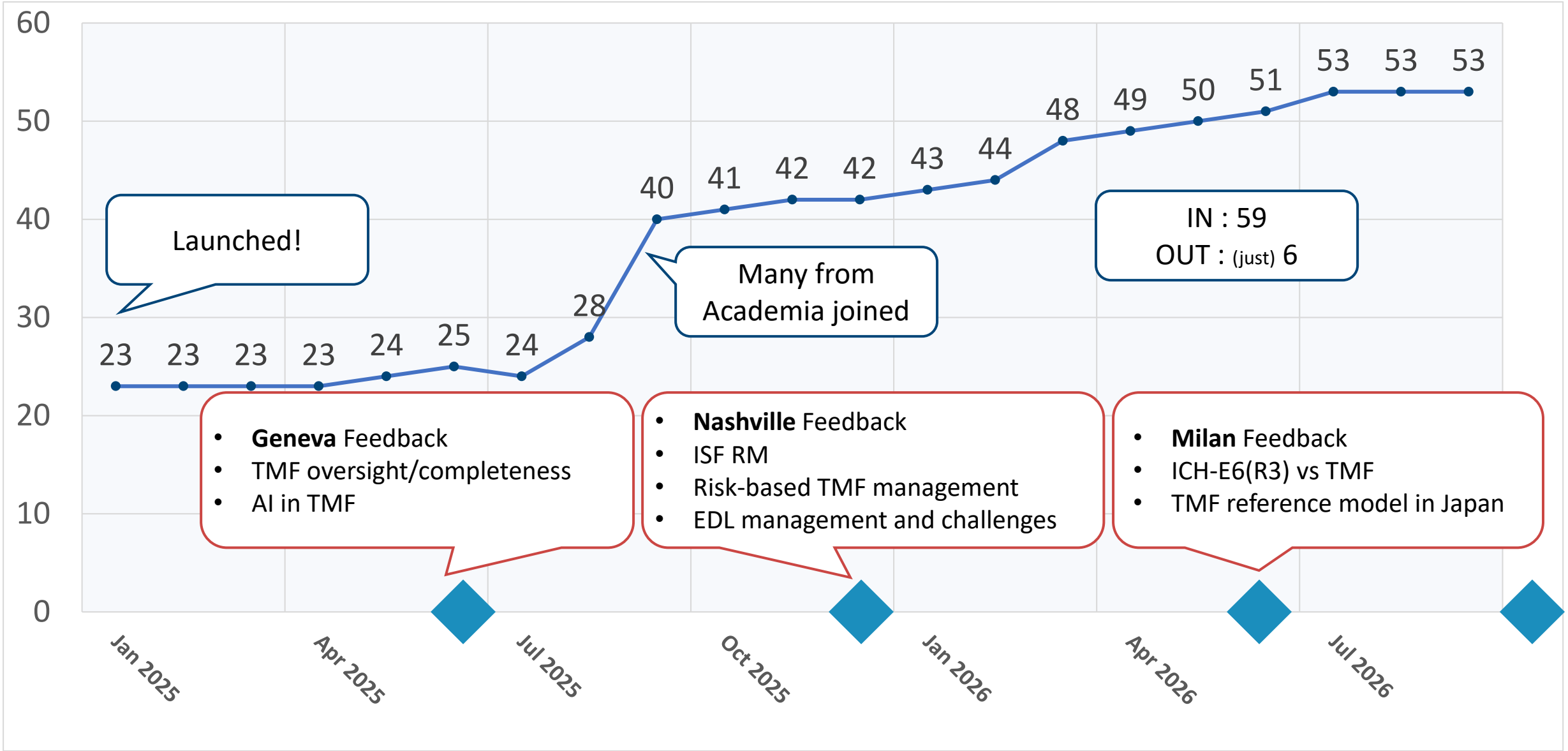
Yuto Kanda

JP TMF community X RAY

Type	organization	# members
Pharma	Asahi Kasei therapeutics, Chugai, Merck KGaA, KM Biologics, Novartis, Otsuka Pharmaceutical Factory, SinoCellTech & Sumitomo Pharma	**10**
CRO	A2 Healthcare, CMIC, Linical & PPD-SNBL	**8**
Service Provider	Agatha, ClinCloud, CRS cube, Medidata, Transperfect&Veeva	**9**
Academia	Japan Institute for Health Security, Juntendo University, Keio University Hospital, Kobe University Hospital, Nagoya University Hospital, Mie University Hospital, Translational Research Center for Medical Innovation, Yokohama City University Hospital, Nagasaki University Hospital	**24**
Consulting	inSeption Group	**1**

F2F WS

Total # of the community members &event history



CDISC TMF/ISF model presentation finished in Sep!



- Opportunity given to make a presentation about **sites' challenges and TMF/ISF model for JP investigators and site staff**
- Members on the stage
  - **2 Study-coordinator managers, Project/study manager, Data manager** and me
- **160+** attended in the room
- Quick poll highlighted audiences' challenges for record management. They suffer from lack of;
  - Consistency/standard index
  - Standard process
  - Comprehensive training
  - Budget for system implementation etc…
- They're eager to learn more about the models, We're searching next conference opportunities….

TO BE CONTINUED!

F2F WS June2026 Timetable : Side A

#	Agenda	Presenter	Stype	Duration	start	close
0	Lunch	n/a	F2F Only	60	12pm	1pm
1	Introduction	MC	Hybrid	5	**1pm**	
2	**EU interchange Feedback**	Yuto & Kae	Hybrid	40	1:05	
3	**Sub team update : Record management in academia**	Sub team	Hybrid	10	1:45	
4	**Sub team update Sponsor-CRO collaboration**	Sub team	Hybrid	10	1:55	
5	Group photo&Break #1	NA	n/a	30	2:05	
6	**ICH-E6(R3) vs TMF survey results review**	Sub team	Hybrid	60	2:35	
7	Break #2		n/a	10	3:35	
8	**TMF RM survey results review & Discussion**	Sub team	Hybrid	40	3:45	
9	Closing	MC	Hybrid	10	4:25	
10	Dinner		F2F Only		5pm	8pm

F2F WS June2026 Timetable : Side B

#	Agenda	Presenter	Stype	Duration	start	close
0	**Lunch**	n/a	F2F Only	**60**	12pm	1pm
1	Introduction	MC	Hybrid	5	**1pm**	
2	EU interchange Feedback	Yuto & Kae	Hybrid	40	1:05	
3	Sub team update : Record management in academia	Sub team	Hybrid	10	1:45	
4	Sub team update Sponsor-CRO collaboration	Sub team	Hybrid	10	1:55	
5	**Group photo & Break #1**	NA	n/a	**30**	2:05	
6	ICH-E6(R3) vs TMF survey results review	Sub team	Hybrid	60	2:35	
7	Break #2		n/a	10	3:35	
8	TMF RM survey results review & Discussion	Sub team	Hybrid	40	3:45	
9	Closing	MC	Hybrid	10	4:25	
10	**Dinner**		F2F Only	**180**	5pm	8pm

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June2025



Dec2025



June2026





-Photos are the best records to prove community activities
-It helps a lot to engage people, both locally & globally!

JP TMF Community RM Sub-Team Survey: Practitioner Insights for Future TMF Standards

From Local Practice to Global Impact

How does the JP TMF Community RM Sub-Team turn practitioner experience into future TMF alignment?
We proactively examine current practice and identify interpretation gaps for future harmonization.



Observe



Challenge



Align



Influence

Local experience today becomes global TMF insight tomorrow.

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Why conduct the survey?

The goal was not to identify a "correct" filing approach, but to understand where interpretation varies and why.

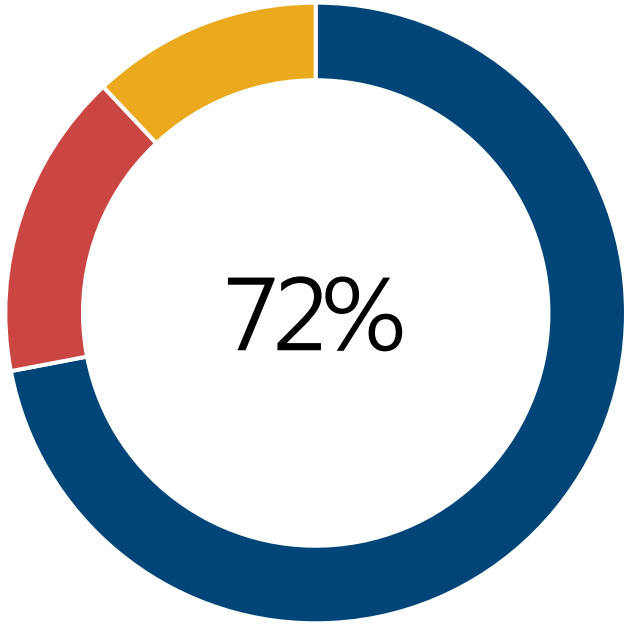
- One reference, many perspectives
- Local realities influence implementation
- Understanding diversity strengthens alignment

25	21	4	Zones 1–5
Participating organizations	Pharmaceutical companies	CROs	Primary survey focus

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FINDING 1: TMF RM Is the Shared Foundation in Japan

Q: How widely is the TMF Reference Model used across your organization?



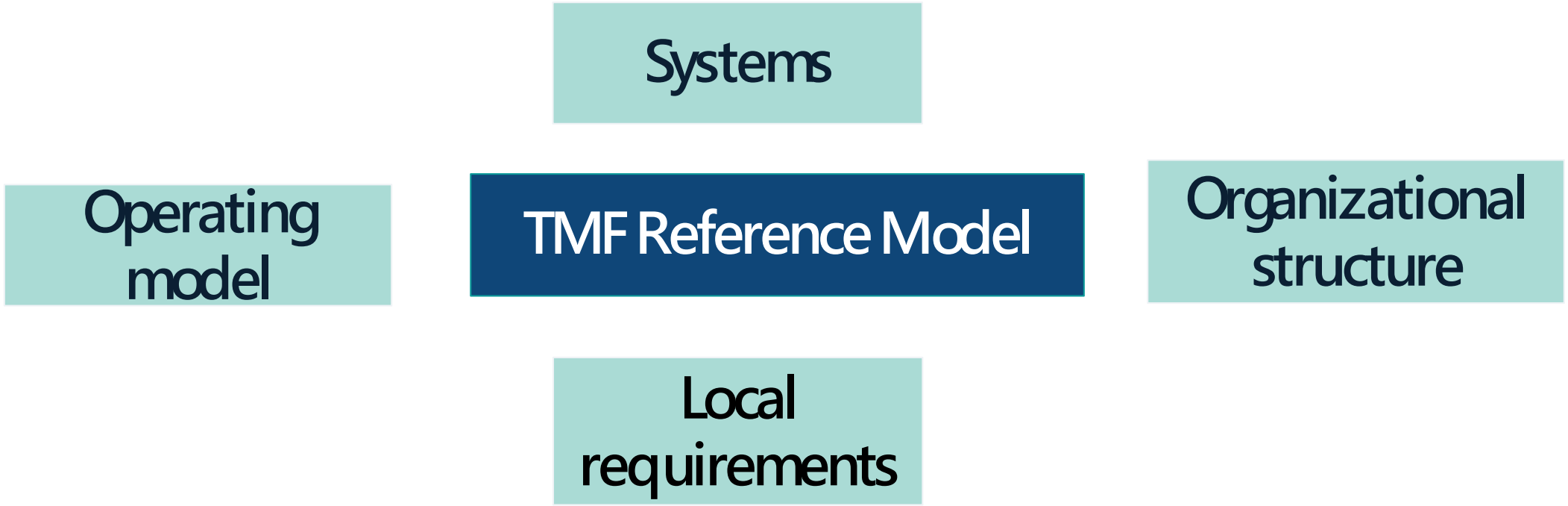
18 of 25 organizations use the TMF RM across all trials

WHAT THIS TELLS US:

From adaptation → to consistent implementation

A Shared Foundation Already Exists

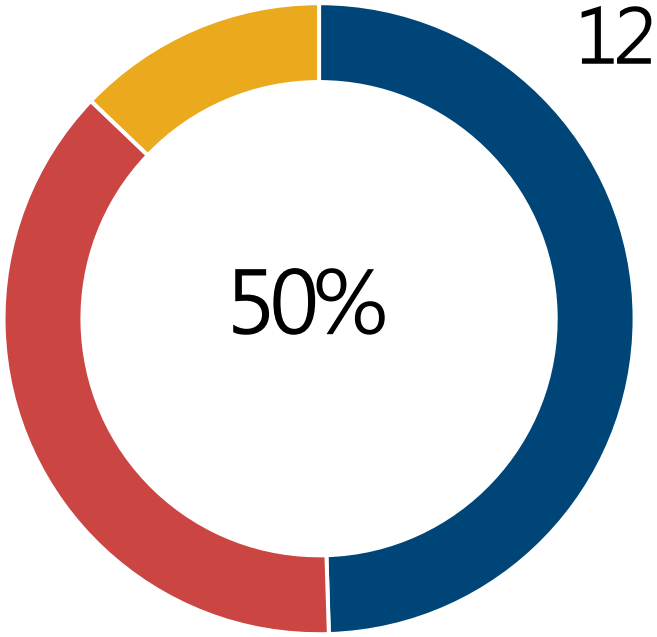
One Reference Model. Many Operating Conditions.



FINDING 2: Customization Reflects Operating Reality

Most organizations remain close to the standard model, while others adapt it to their operating needs.

5. To what extent has your organization customized the TMF Reference Model?



12 organizations remain close to TMF RM structure.

CUSTOMIZATION = Extending the TMF RM Structure

What Drives Customization?

Takeaway: Some variation reflects local needs; other variation reflects organizational choices.

5. Please tell me about customizing the TMF Reference Model.

External & Local Constraints

- System configuration limitations
- Sponsor–CRO system interfaces
- **Japan-specific regulatory / operational requirements**
- Legacy technology or taxonomy constraints

Workflow Optimization ~5–15%

- Consolidating related Artifacts / removing some artifacts
- Simplifying navigation
- **Aligning with internal workflows**

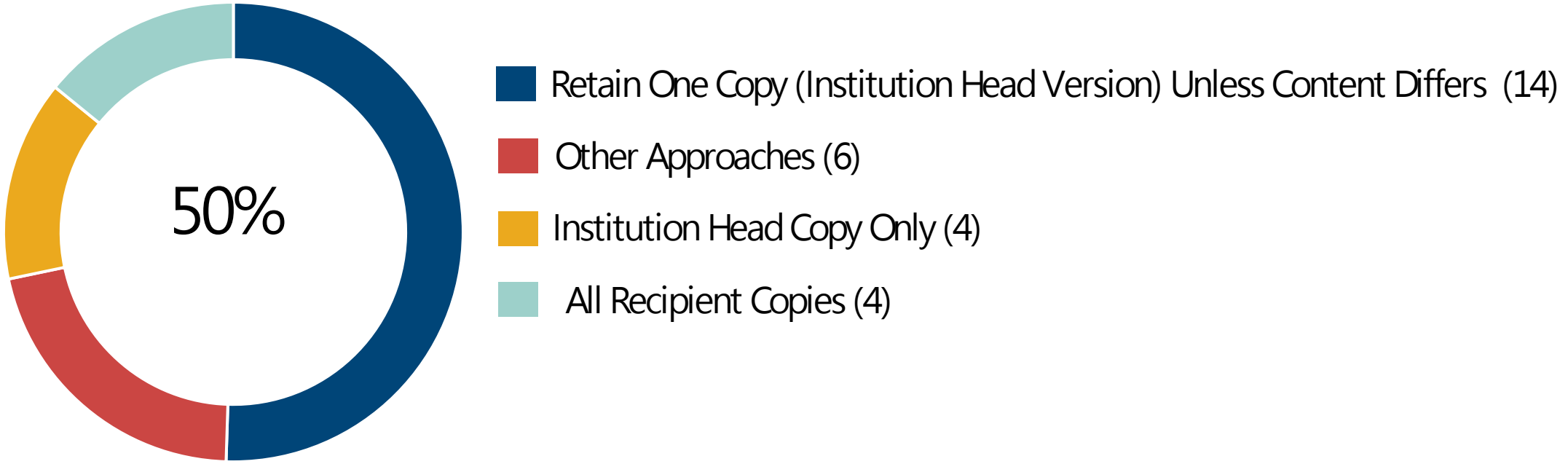
Taxonomy & Terminology Alignment up to ~50%

- Adding or restructuring Artifacts / Sub-artifacts
- **Aligning with Japanese regulatory terminology**
- Matching internal SOP terminology
- Aligning with organizational document names

FINDING 3: Standardized Communication, Different Filing Decisions

The document is standardized, yet organizations differ in deciding which recipient copy constitutes TMF evidence.

5. How do organizations retain safety Notification form(JP standard) if the same safety information is sent to multiple stakeholders?



FINDING 3: Unified Forms*, Multiple Evidence Decisions

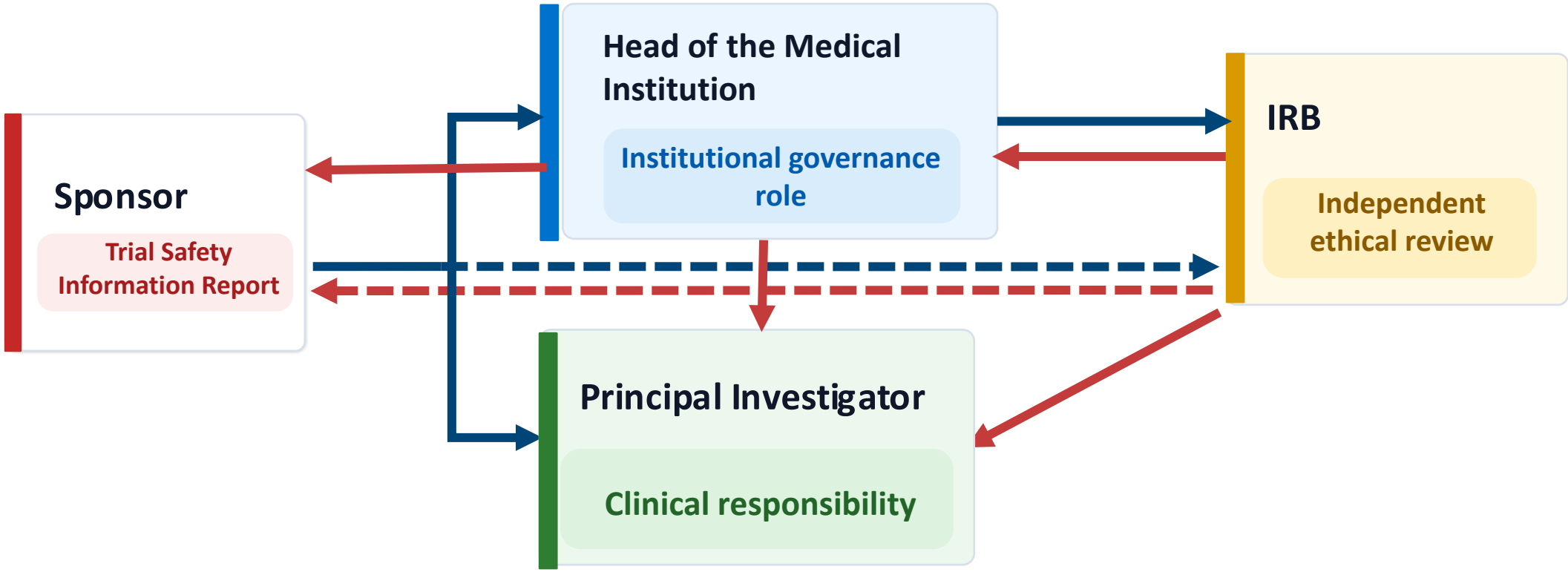
*Government-endorsed standard templates to harmonize clinical trial documentation and processes.

One sponsor-issued form, multiple recipients, multiple responsibilities.

1 Safety distribution

2 Institutional and clinical review

3 Independent ethical review



When Does a Form Become TMF Evidence?

Safety Information Report

Sponsor issued reports

Multiple recipients notified

IRB Review Result Notification

IRB review complete

Institution Head decision communicated

One record or multiple recipient copies?

Investigator & Staff List

PI prepares list

Institution Head approves

PI decision or final approved version?

Next step: Build greater consensus on what constitutes TMF evidence through further survey.

How our community Turns Experience into Evolution

Takeaway: Local experience strengthens global standards when learning flows both ways.



Makes implementation challenges visible

Surfaces recurring implementation challenges

Creates informed cross-organizational dialogue

Identify opportunities for more streamlined practices.

Translates local experience into structured feedback

Provides structured feedback to the global community

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Thank You!



Questions?

